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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,549	11/17/2003	John B. McCraw	JBM 1	5070

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AARON PASSMAN
9632 WINDOM POINT AVE
LAS VEGAS, NV 89129

EXAMINER

HAND, MELANIE JO

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 06/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/715,549

Applicant(s)

MCCRAW, JOHN B.

Examiner

Melanie J. Hand

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

The affidavit under 37 CFR 1.132 filed February 8, 2006 is insufficient to overcome the rejections of claims 1-20 based upon prior art references applied under 35 U.S.C. 102, 103 as set forth in the last Office action because: applicant's affidavit is directed toward perceived point of novelty (i.e. a surgical drain that does not require a supporting structure) which is not present in the claims. There is no claim language specifically setting forth an absence of a supporting structure. In fact, to the contrary, claims 17, 19 and 22 set forth an introducer for said drain, which necessarily provides a support structure to said drain to stabilize said drain while guiding said drain to a site, and remains to provide support even while the drain is placed at the site, where it remains temporarily until such time as a user elects to remove said introducer.

Response to Arguments

Applicant's arguments, see Remarks, filed March 3, 2006, with respect to the rejection(s) of claim(s) 1-7,9,11-15 and 17-20 under 35 U.S.C. 102 and the rejection of claims 8 and 16 under 35 U.S.C. 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of a different interpretation of a previously applied prior art reference.

Applicant's arguments with respect to the rejection of claims 21 and 22 and the amendment to overcome said rejection have been fully considered but they are not persuasive. Righetti teaches that sheath 3 is coupled to a mechanical aspiration unit that functions as an external collector and therefore the prior art of Righetti still anticipates claims 21 and 22.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3, 9-12, and 17-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Righetti (U.S. Patent No. 6,605,068).

With respect to **claims 1-3**: Righetti teaches a gravity drainage cord formed by placing a plurality of strands 2 (fibers) (each elongate and having an internal end, an external end and a middle therebetween) loosely into a tubular sheath 3 (introducer) thereby gathering said strands at their external ends. The internal ends of said strands are placed in the wound via said sheath wherein each strand is capable of spreading or being spread divergently of the other strands (Col. 1, lines 64, 65, Col. 2, lines 8,9, 25-28) Righetti teaches that the portion of sheath 3 intended for placement at a wound site is comprised of a plurality of drainage holes and that sheath 3 that is operatively connected to the external ends of said strands is configured to enable coupling (fluid communication) to mechanical aspiration units that (external collector and source of vacuum (claim 2)) accumulate bodily fluid guided along, about and amongst the strands from their internal ends along the middle and to the gathered together external ends during drainage of fluid from inside a wound or surgical site. (Col. 2, lines 12-14, 28-30)

With respect to **claim 4**: Righetti teaches that the strands 2 are comprised of silk of the type used for surgical sutures (biocompatible natural substance) (Abstract).

With respect to **claims 9-12,17-19,21,22**: Please see the rejection of claim 1 in addition to the following: With respect to the steps of accumulating fibers and gathering said fibers together at

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their external ends, Righetti teaches a gravity drainage cord formed by placing a plurality of strands 2 (each having an internal end, an external end and a middle therebetween) loosely into a tubular sheath 3 (introducer) thereby gathering said fibers at their external ends. The internal ends of said strands placed in the wound via said sheath wherein (Col. 1, lines 64, 65, Col. 2, lines 8,9, 25-28) With respect to the step of positioning an external collector in fluid communication with the gathered external ends, Righetti teaches that the portion of sheath 3 intended for placement at a wound site is comprised of a plurality of drainage holes and that sheath 3 that is operatively connected to the external ends of said fibers is configured to enable coupling (fluid communication) to mechanical aspiration units (external collector that can be held) that accumulates bodily fluid guided along, about and amongst the fibers from their internal ends along the middle and to the gathered together external ends during drainage of fluid from inside a wound or surgical site. (Col. 2, lines 12-14, 28-30)

With respect to **claim 20**: Since Righetti teaches silk strands that are capable of being spread divergently of one another, the plurality of middle fibers in the middle are thus capable of flexing and shifting with relative to one another so that the cross-section thereof approximates the cross section of the percutaneous incision at a surgical site through which said plurality of middle fibers passes in the process of guiding drainage during healing.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 8 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Righetti ('068).

With respect to **claims 8,16**: Righetti does not explicitly teach that said mechanical aspiration unit comprises a regulator for controlling the flow of suction to the drain, however it is well known in the art to provide a suction source with a means for turning said source off and on (regulator) at least manually (if not also automatically), therefore it would be obvious to one of ordinary skill in the art to provide a regulator to the mechanical aspiration unit of Righetti.

Claims 5-7 and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Righetti (U.S. Patent No. 6,605,068) in view of Feibus.

With respect to **claim 5,13**: Righetti does not teach that said strands are bioabsorbable. Feibus teaches a woven surgical drain having absorbable filler material 7. (Col. 4, lines 66-68, Col. 7, lines 17-21, 32-34) It would be obvious to one of ordinary skill in the art to provide the drain of Righetti with absorbent filler material in addition to the strands which are taught by Righetti to be treated so as not to be nonabsorbent in order to effect improved drainage. Adding said filler material would provide the additional advantage of absorbing excess exudates from the wound that cannot be borne by the strands, which are of a fine, lightweight material.

With respect to **Claims 6,7,14,15**: Righetti teaches that said silk strands are treated but does not teach that they are treated with anticoagulant or anti-thrombogenic agents. Feibus teaches that drain fabric 15 is treated with antimicrobial and antithrombogenic agents. (Col. 6, lines 1-4) Feibus therefore teaches that the drain prevents thrombosis and coagulation, at the wound site,

therefore it would be obvious to one of ordinary skill in the art to modify the strands and/or sheath taught by Righetti so as to be treated with anticoagulant or antithrombogenic compositions to prevent these conditions which would interfere with wound drainage and healing and cause harmful physiological conditions for the user.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

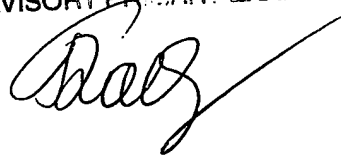
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie J Hand
Examiner
Art Unit 3761

MJH

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Tatyana', is written over the printed name and title of the Supervisory Primary Examiner.